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STATEMENT BY APPLICANT**

( Not for submission under 37 CFR 1.99)

Application Number	10530794
Filing Date	2005-04-08
First Named Inventor	Francis Thomas Boyle
Art Unit	1614
Examiner Name	James D. Anderson
Attorney Docket Number	100864-1P US

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/M. L. S./	1	5770599		1998-06-23	Gibson	
/M. L. S./	2	5457105		1995-10-10	Barker	
/M. L. S./	3	5616582		1997-04-01	Barker	

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/M. L. S./	1	20030092757	A1	2003-05-15	Singh et. al.	

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/M. L. S./	1	2006/056760	WO	A1	2006-06-01	AstraZeneca AB		<input type="checkbox"/>

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/M. L. S./	2	1424080	EP	A1	2004-06-02	Takeda Chemical Industries		<input type="checkbox"/>
	3	0823900	EP	B1	1998-02-18	AstraZeneca AB		<input type="checkbox"/>
	4	0566226	EP	B1	1995-11-08	Zeneca Limited		<input type="checkbox"/>
	5	2003/072108	WO	A1	2003-09-04	AstraZeneca AB		<input type="checkbox"/>
	6	2001/76586	WO	A1	2001-10-18	AstraZeneca AB		<input type="checkbox"/>
	7	2003/088971	WO	A1	2003-10-30	AstraZeneca AB		<input type="checkbox"/>
	8	2004/014426	WO	A1	2004-02-19	AstraZeneca AB		<input type="checkbox"/>
	9	2005/004872	WO	A1	2005-01-20	AstraZeneca AB		<input type="checkbox"/>
	10	2005/117888	WO	A1	2005-12-15	AstraZeneca AB		<input type="checkbox"/>
↓ MLS	11	2005/063735	WO	A1	2005-07-14	Merck Patent GMBH		<input checked="" type="checkbox"/>
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Examiner Initials*	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>5</sup>
/M. L. S./		MORRIS MICHAEL J ET AL: "Clinical approaches to osseous metastases in prostate cancer." The Oncologist, 2003, pages 161-173, vol. 8, no. 2	<input type="checkbox"/>
	2	ROSANO LAURA A ET AL: "Therapeutic targeting of the endothelin a receptor in human ovarian carcinoma," Cancer Research, 15 May 2003 (2003-05-15), pages 2447-2453, vol. 63, no. 10, XP002365689	<input type="checkbox"/>
	3	WALCZAK J R ET AL: "Pharmacological Treatments for Prostate Cancer," Expert Opinion on Investigational Drugs, 2002, pages 1737-1748, Vol . 11, no. 12, Ashley Publications, Ltd., London, GB, XP009008862	<input type="checkbox"/>
	4	ROSANO, LAURA ET AL, "ZD4054, a specific antagonist of the endothelin A receptor, inhibits tumor growth and enhances cytotoxicity of paclitaxel in human ovarian carcinoma in vitro and in vivo," April 16-20, 2005, AACR, Anaheim/Orange County, CA	<input type="checkbox"/>
	5	CURTIS, N. ET AL: "ZD4054 specifically inhibits endothelin A receptor-mediated anti-apoptotic effects, but not endothelin B receptor-mediated pro-apoptotic effects," September 28-October 1, 2004, AACR-NCI-EORTC, Geneva, Switzerland	<input type="checkbox"/>
	6	LIU, GLENN ET AL, "Tolerability profile of ZD4054 is consistent with the effects of endothelin A receptor-specific antagonism," May 13-17, 2005, ASCO Annual Meeting, Orlando, Florida	<input type="checkbox"/>
	7	MORRIS, C. ET AL, "ZD4054: specificity for endothelin A receptor following single-dose administration in healthy volunteers," September 28-October 1, 2004, AACR-NCI-EORTC, Geneva, Switzerland	<input type="checkbox"/>
	8	DREICER, R. ET AL., "ZD4054 specifically inhibits endothelin A receptor-mediated effects but not endothelin B receptor-mediated effects," February 17-19, 2005, ASCO Prostate Cancer Symposium, Orlando, Florida	<input type="checkbox"/>
	9	TODD, MARTIN ET AL, "Metabolite Factories: Use of microbial systems to generate metabolites of an endothelin receptor antagonist," July 3-8, 2005, Biotrans 2005, Delft, The Netherlands	<input type="checkbox"/>
↓ MLS	10	MORRIS, CD ET AL. "Specific inhibition of the endothelin A receptor with ZD4054: clinical and preclinical evidence," British Journal of Cancer, 2005 92, 2148-2152	<input type="checkbox"/>

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/M. L. S.	11	CURTIS, N. ET AL, "ZD4054 blocks ET-1-stimulated phosphorylation of p44/42 mitogen-activated protein kinase and proliferation of osteoblast cells," April 16-20, 2005, AACR, Anaheim/Orange County, CA	<input type="checkbox"/>
	12	MORRIS, C.D. ET AL, "ZD4054 reduces endothelin-1-induced forearm vasoconstriction in healthy male volunteers," April 16-20, 2005, AACR, Anaheim/Orange County, CA	<input type="checkbox"/>
	13	ROSANO, LAURA, "Combined targeting of the endothelin receptor and the epidermal growth factor receptor in ovarian cancer shows enhanced antiproliferative effects," April 1-5, 2006, AACR 2006, Washington, DC	<input type="checkbox"/>
	14	CURWEN, J.O., "ZD4054 : a specific endothelin A receptor antagonist with potential utility in prostate cancer and metastatic bone disease," European Journal of Cancer, November 2002 (2002-11), vol. 38, , page S102, Pergamon Press, Oxford, GB, XP004403782	<input type="checkbox"/>
↓ MLS	15	NELSON, J.B., "The role of endothelin-1 and endothelin receptor antagonists in prostate cancer," British Journal of Urology, 2000, pages 45-48, 85, Suppl 2	<input type="checkbox"/>

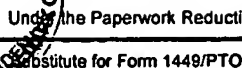
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Examiner Signature	/Marcos Sznaidman/	Date Considered	09/06/2007
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**SHEET 1 of 5**


**Complete if Known**

Application Number	10/530,794
Filing Date	Not yet assigned
First Named Inventor	Boyle, Francis Thomas
Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket No.	100864-1P US

## U.S. PATENT DOCUMENTS

Examiner 'Initials'	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code <sup>2</sup> (if known)			
M. L. S.	US1	US- 5,464,853	11-07-1995	ImmunoPharmaceuticals, Inc.	
↓	US2	US- 5,514,691	05-07-1996	ImmunoPharmaceuticals, Inc.	
	US3	US- 2002/0055457	05-09-2002	Janus, Todd J.	
	US4	US- 5,843,902	12-01-1998	Praecis Pharmaceuticals, Inc.	
	US5	US- 2005/0014769	01-20-2005	Osswald, Mathias	

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
/M. L. S.	AA	EP 510,526 A1 +English Abstract	10-28-1992	F. Hoffmann-La Roche & Co.		<input type="checkbox"/>
	AB	EP 526,708 A1 +English Abstract	02-10-1993	F. Hoffmann-La Roche AG		<input type="checkbox"/>
	AC	EP 558,258 A1	09-01-1993	E.R. Squibb & Sons, Inc.		<input type="checkbox"/>
	AD	EP 569,193 A1	11-10-1993	E.R. Squibb & Sons, Inc.		<input type="checkbox"/>
	AE	EP 640,596 A1	03-01-1995	Bristol-Myers Squibb Company		<input type="checkbox"/>
	AF	WO 96/09818 A1	04-04-1996	Merck & Co., Inc.		<input type="checkbox"/>
	AG	WO 94/27979 A1	12-08-1994	Immunopharmaceuticals, Inc.		<input type="checkbox"/>
	AH	WO 99/48530 A1	09-30-1999	Merck & Co., Inc.		<input type="checkbox"/>
	AI	WO 99/56761 A1	11-11-1999	Davar, Gudarz		<input type="checkbox"/>
	AJ	WO 00/21509 A2	04-20-2000	Imperial College Innovations Limited		<input type="checkbox"/>
	AK	WO 00/36918 A1	06-29-2000	Marine Polymers Technologies, Inc.		<input type="checkbox"/>
	AL	WO 01/00198 A2	01-04-2001	California Institute of Technology		<input type="checkbox"/>
	AM	WO 00/67024 A1	11-09-2000	New York University		<input type="checkbox"/>
	AN	WO 01/91736 A2	12-06-2001	Warner-Lambert Company		<input type="checkbox"/>
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SHEET 2 of 5

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Application Number	10/530,794
Filing Date	Not yet assigned
First Named Inventor	Boyle, Francis Thomas
Art Unit	Not yet assigned
Examiner Name	Not yet assigned
Attorney Docket No.	100884-1P US

**U.S. PATENT DOCUMENTS**

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/M. L. S/	AO	WO 02/11713 A2	02-14-2002	Abbott Laboratories		<input type="checkbox"/>
	AP	WO 02/069906 A2	09-12-2002	Cellegy Pharmaceuticals Inc.		<input type="checkbox"/>
	AQ	WO 02/074034 A2	09-26-2002	Boehringer Ingelheim Pharma KG		<input type="checkbox"/>
	AR	WO 02/80960 A2	10-17-2002	Medical Research Council		<input type="checkbox"/>
	AS	WO 02/085351 A1	10-31-2002	Abbott Laboratories		<input type="checkbox"/>
	AT	WO 03/006041 A1 +English Abstract	01-23-2003	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>
	AU	WO 03/009805 A2	02-06-2003	Brigham & Women's Hospital, Inc.		<input type="checkbox"/>
	AV	WO 03/015820 A1 +English Abstract	02-27-2003	Takeda Chemical Industries, Ltd.		<input type="checkbox"/>
	AW	WO 03/039539 A2	05-15-2003	Merck Patent GMBH		<input type="checkbox"/>
	AX	WO 03/045434 A2	06-05-2003	The Board of Trustees of the University of Illinois		<input type="checkbox"/>
	AY	WO 95/26957 A1	10-12-1995	Zeneca Limited		<input type="checkbox"/>
	AZ	EP 682,016 A1	11-15-1995	AstraZeneca AB		<input type="checkbox"/>
	BA	GB 2,295,616 A	06-05-1996	Zeneca Limited		<input type="checkbox"/>
Examiner Signature	/Marcos Sznaidman/			Date Considered	09/06/2007	

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Application Number 10/530,794

Filing Date Not yet assigned

First Named Inventor Boyle, Francis Thomas

Art Unit Not yet assigned

Examiner Name Not yet assigned

Attorney Docket No. 100864-1P US

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	BI	WO 2005/080403 A2	09-01-2005	AstraZeneca AB		<input type="checkbox"/>
	BJ	WO 01/60370 A1 and English equivalent EP1256344	08-23-2001	Yamanouchi Pharmaceutical Co. Ltd.		<input type="checkbox"/>
	BK	WO 02/49630 A2	06-27-2002	Bristol-Myers Squibb Company		<input type="checkbox"/>
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	First Named Inventor	Boyle, Francis Thomas
	Art Unit	Not yet assigned
	Examiner Name	Not yet assigned
SHEET 4 of 5		Attorney Docket No. 100864-1P US

NON PATENT LITERATURE DOCUMENTS			
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/M. L. S.	AA	NELSON JB "Endothelin-1 Production and Decreased endothelin B Receptor Expression in advanced Prostate Cancer" Cancer Research 56, 663-668, February 15, 1996	<input type="checkbox"/>
	AB	KROODSMA JM; <i>et al</i> "Endothelinen: mogelijk een nieuw farmacologisch aangrijpingspunt bij hart-en vaatziekten, nierziekten en oncologische aandoeningen" Nederlands Tijdschrift Voor Geneeskunde, 1997 Sept 20, 141, 38, 1806-10 +English Abstract	<input type="checkbox"/>
	AC	An abstract reporting the symposium "Endothelin Inhibitors: Exploring Novel Therapeutics" Meeting Report (June 25, 1999) Washington DC, USA, June 7-8 1999	<input type="checkbox"/>
	AD	BOVEN E An abstract by reporting from the "American Society of Clinical Oncology - 35 <sup>th</sup> Annual Meeting (Part I)" Meeting Report (Sept 13, 2001), Atlanta, GA, USA, May 15-18 1999	<input type="checkbox"/>
	AE	MCKINNON C An abstract by reporting from the "American Society of Clinical Oncology - 35 <sup>th</sup> Annual Meeting (Part IV)" Meeting Report (Sept 13, 2001), Atlanta, GA, USA, May 15-18 1999	<input type="checkbox"/>
	AF	ADENIYI A An abstract by reporting from the "American Urological Association - 94 <sup>th</sup> Annual Meeting" Meeting Report (Aug 26, 1999), Dallas, TX, USA, May 1-6 1999	<input type="checkbox"/>
	AG	BOVEN E "American Society of Clinical Oncology - 35 <sup>th</sup> Annual Meeting" IDrugs, (1999) 2/7 (617-619), Atlanta, GA, USA, May 15-18 1999	<input type="checkbox"/>
	AH	MCKINNON C "Topoisomerase Inhibitors and Other New Agents", IDrugs, (1999) 2/7 (629-632) Atlanta, GA, USA, May 15-18 1999	<input type="checkbox"/>
	AI	ADENIYI A "American Urological Association - 94 <sup>th</sup> Annual Meeting" IDrugs, (1999) 2/7 (656-658), Dallas, TX, USA, May 1-6 1999	<input type="checkbox"/>
	AJ	NELSON JB "Editorial: Endothelin Receptor Antagonists in the Treatment of Prostate Cancer" The Prostate 49: 91-92 (2001) Pittsburgh, PA USA	<input type="checkbox"/>
	AK	NELSON JB; <i>et al</i> "The Role of the Endothelin Axis in Prostate Cancer" The Prostate Journal. Volume 1, Number 3, May / June 1999, 126-130	<input type="checkbox"/>
	AL	NELSON JA; <i>et al</i> "Identification of Endothelin-1 in the Pathophysiology of Metastatic Adenocarcinoma of the Prostate" Nature Medicine, Vol 1, No 9, September 1995, 944-949	<input type="checkbox"/>
	AM	CURWEN JO; <i>et al</i> "ZD4054: A Specific Endothelin A Receptor Antagonist with Potential Utility in Prostate Cancer and Metastatic Bone Disease" EORTC-NCI-AACR, Frankfurt, Germany AstraZeneca Poster presented 19-22 November 2002	<input type="checkbox"/>
	AN	BAGNATO A; <i>et al</i> "Autocrine Actions of Endothelin-1 as a Growth Factor in Human Ovarian Carcinoma Cells" Clinical Cancer Research, 1995, Vol 1, 1059-1066	<input type="checkbox"/>
Examiner Signature	/Marcos Sznaidman/		Date Considered 09/06/2007

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Substitute for Form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(Use as many sheets as necessary)</i>	<b>Complete if Known</b>	
	Application Number	10/530,794
	Filing Date	Not yet assigned
	First Named Inventor	Boyle, Francis Thomas
	Art Unit	Not yet assigned
	Examiner Name	Not yet assigned
SHEET 5 of 5		Attorney Docket No. 100864-1P US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
/M. L.	AO S./	CARDUCCI MA; <i>et al</i> "Endothelin Receptor Antagonist: ABT-627 Prostate Cancer: Initial Trial Results" The Journal of Urology, Vol. 161, no. 4, SUPPL, April 1999, page 176, Baltimore, MD, USA	<input type="checkbox"/>
	AP	DERWENT AN 2001-565331, XP002271565	<input type="checkbox"/>
	AQ	JARVIS MF; <i>et al</i> "ABT-627, an Endothelin ET <sub>A</sub> Receptor-Selective Antagonist, Attenuates Tactile Allodynia in a Diabetic Rat Model of Neuropathic Pain" European Journal of Pharmacology, 2000, Vol 388, 29-35, Abbott Park, IL USA	<input type="checkbox"/>
	AR	WU-WONG JR "Endothelin Attenuates Apoptosis in Human Smooth Muscle Cells" Biochemical Journal, 1997, Vol 328, No. 3, 733-737, Abbott Park, IL USA	<input type="checkbox"/>
	AS	SPINELLA, F "Endothelin-1 Induces Vascular Endothelial Growth Factor by Increasing Hypoxia-Inducible Factor-1a in Ovarian Carcinoma Cells" J Biological Chemistry, 2002, 277 (31), 27850-27855, Rome Italy	<input type="checkbox"/>
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Examiner Signature	/Marcos Sznajdman/		Date Considered 09/06/2007

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<b>INFORMATION DISCLOSURE STATEMENT</b> Form PTO-1449	Application Details	
	First Named Inventor	Thomas Francis Boyle
	Filing Date	Herewith
	Application Serial No.	Not yet assigned
	Examiner Name	Not yet assigned
	Group Art Unit	Not yet assigned
	Attorney Docket No.	100864-1P US

U.S. PATENT DOCUMENTS							
Examiner Initials	Desig. ID	Document Number	Publication Date	Name	Class	Sub Class	Filing Date if Appropriate
	AA	2002/107 284	August 8, 2002				

FOREIGN PATENT DOCUMENTS									
Examiner Initials	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Sub Class	Filing Date	Abstract Only	English Language
/M. L. S./	AB	99/55683	November, 4, 1999	WO					Yes

OTHER DOCUMENTS (include Author, Title, Date and Place of Publication)		
Examiner Initials	Desig. ID	Document
/M. L. S./	AC	CARDUCCI M A ET AL : "ENDOTHELIN RECEPTOR 1-16 ANTAGONIST, ABT-627, FOR PROSTATE CANCER : INITIAL TRIAL RESULTS" JOURNAL OF UROLOGY, BALTIMORE, MD, US, vol . 161, no . 4, SUPPL, April 1999 (1999-04), page 176 XPOO1037609 ISSN : 0022-5347

Examiner Signature	/Marcos Sznaidman/	Date Considered	09/06/2007
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\*EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.